

K 073224

**510(k) Summary**

**Applicant:**

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**Applicant Correspondent:**

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**Date Summary Prepared:**

October 12, 2007

**Proprietary Name of Device:**

Oral-B® "sub-brand" manual toothbrush  
(i.e. CrossAction, Advantage, Pulsar, Pro-Health)

**Generic/Classification Name:**

Toothbrush, Manual

**Product Code (Classification):**

EFW (Class I, 21CFR 872.6855)

**Legally Marketed Predicate Devices:**

Toothbrush, Manual EFW (21 CFR 872.6855)  
Toothbrush, Power JEQ (21 CFR 872.6865) **K061351**

**Device Description and Technical Characteristics:** The Oral-B® toothbrush is a manual toothbrush comprised of a shaft with synthetic bristles at one end. The bristles are arranged in a pattern to achieve effective mechanical plaque removal. Some of the bristle tufts have a wear indicator function. These Indicator bristles are colored with FDA approved colorant, FD&C Blue No. 2.

While manual toothbrushes are exempt devices, we believe the expansion of the indication to include for use of treating and preventing gingivitis may exceed the limitations of the 510(k) exemption. The expansion of the indication (treating and preventing gingivitis) is the only change from the currently marketed exempt device. There are no changes to the material, design or manufacturing process.

**Indication for Use:** To promote good oral hygiene including plaque removal and treating and preventing gingivitis.

**Testing:** Oral-B® manual toothbrushes have been tested in numerous controlled clinical studies. These trials evaluated the effectiveness of the manual brush at removing plaque and improving and maintaining gingival health. In addition oral soft and hard tissue safety was assessed. Collectively, these studies demonstrate that Oral-B® manual toothbrushes are effective at treating and preventing gingivitis via the physical/mechanical removal of plaque.

**Conclusions:** The information provided supports the safety and effectiveness of Oral-B® manual toothbrushes and their substantial equivalence to the predicate devices without raising any new safety and effectiveness issues.

## Bibliography

1. M. J. Cronin, W. Dembling, N. Conforti, J. Lieberman, M.A. Cugini, P. Warren: A single use and 3-month clinical investigation of the comparative efficacy of a battery-operated power toothbrush and a manual toothbrush. Special issue article Am J Dent 2001; 14:19B-24B
2. N. Sharma, J. Qaish, H. Galustians, D. King, M. Low, D. Jacobs, D. Weber: A 3-month comparative investigation of the safety and efficacy of a new toothbrush: Results from two independent clinical studies. Am J. Dent 2000, 13: Special Issue, 27A-32A
3. A Six-Week clinical comparison of the Safety and Efficacy of Two manual Toothbrushes Hilltop Research, Inc. West palm Beach, Florida, Final Report
4. Nathoo S., Chaknis P., Petrone M., DeVizio W and Volpe AR: A Clinical Comparison of the Gingivitis Reduction and Plaque-removal Efficacy of a New Manual Toothbrush. Compendium 2004, 25(10) Suppl. 2:37-45
5. Goyal C.R., Quaish J.G. and Galustians L.: Efficacy and Safety of a New Power Toothbrush in a population with Mild to Moderate Gingivitis. J Clin Dent 2007, 18:65-69
6. Yankell S.M., Emling R. and Perez B.: A Six-Month Clinical Evaluation of the Dentrust Toothbrush. J Clin Dent 1996, 7:106-109



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Food and Drug Administration  
9200 Corporate Boulevard  
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Dr. Michael A. Kaminski  
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Re: K073224  
Trade/Device Name: Oral-B® "sub-brand" manual toothbrush  
Regulation Number: 872.6855  
Regulation Name: Manual Toothbrush  
Regulatory Class: I  
Product Code: EFW  
Dated: November 12, 2007  
Received: November 15, 2007

Dear Dr. Kaminski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K 073224

Device Name: Oral-B® "sub-brand" manual toothbrush

Indication For Use:

To promote good oral hygiene including plaque removal and treating and preventing gingivitis.

Prescription Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K073224